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| 10/829,315 | 04/21/2004 | Joel R. Studin | SDF 04-15 | 5670 |

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Stuart D. Frenkel
Suite 330
3975 University Drive
Fairfax, VA 22030

| EXAMINER | |
|---|---|
| SHEIKH, HUMERA N | |

| ART UNIT | PAPER NUMBER |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/829,315 | STUDIN, JOEL R. | |
| | Examiner | Art Unit | |
| | Humera N. Sheikh | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *17-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/04/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### Status of the Application

Receipt of the Response and Amendment after Non-Final Office Action, Applicant's Arguments/Remarks and the Declaration under 37 C.F.R.1.132, all filed 04/28/08 is acknowledged.

Upon further review and consideration, the Non-Final Office Action filed 10/31/07 has been withdrawn. The following are the new grounds of rejection:

Claims 17-25 are pending in this action. Claims 17 and 19 have been amended. Claims 1-16 and 26-54 have been cancelled. Claims 17-25 are rejected.

* * * * *

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 17-21, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Youssefyeh *et al.* (U.S. Pat. No. 5,968,519) in view of Mantelle *et al.* (U.S. Pat. No. 6,562,363).**

**Youssefyeh *et al.* ('519)** teach a method for the treatment of inflammation and pain associated with inflammatory dermatoses (eczema, psoriasis), gingivitis and acute injury with a composition of finely divided powder of safflower seed or its extract contained in a pharmaceutically acceptable carrier (see Abstract); (column 1, lines 10-18). Youssefyeh teach that the method of treatment for the relief of inflammation and/or pain associated with inflammatory dermatoses such as eczema, urticaria, psoriasis and the like comprises topically administering a therapeutically effective amount of a finely divided powder of safflower seed or its extract sufficient to induce alleviation of signs, symptoms or causes of inflammation or pain in a pharmaceutically acceptable carrier (col. 11, line 49 – col. 12, line 58); (col. 13, line 53 – col. 14, line 7); (col. 22, line 64 – col. 24, line 13). Youssefyeh teach that for topical administration, the compositions may contain certain pharmaceutical and therapeutical agents either singularly or in combination of which suitable pharmaceutical/therapeutical agents disclosed include anti-inflammatory corticosteroids, such as progesterone, hydrocortisone, prednisone, triamcinolone and dexamethasone. Additional agents disclosed include anti-inflammatory analgesics, local anesthetics, antibacterial agents and antiseptic agents. It is also taught that the topical compositions can be in the forms of ointments, creams, lotions, solutions,

dressings and patches and slow-release preparations and film-forming preparations (col. 14, lines 19-40); (col. 15, lines 29-60).

Topical formulations can be prepared by combining the finely divided safflower seed or its extract with conventional pharmaceutical carriers or diluents used in topical dry, liquid and cream formulations. Ointments and creams may be formulated with an aqueous or oil base with the addition of suitable thickening or gelling agents (col. 15, lines 29-60). Ointments, pastes, creams and gels may contain excipients such as cellulose derivatives and silicones (col. 15, lines 43-46).

A preferred form of topical delivery is film-forming materials loaded with finely divided powder of safflower seed or its extract. Suitable film-forming materials taught include cellulosic derivatives, such as methylcellulose, hydroxyethyl cellulose, hydroxypropyl cellulose and other synthetic polymers (col. 15, line 61 – col. 17, line 19); and claim 12. Upon application, the formulation is deposited on the desired area and allowed to form a film, which by the presence of water in the skin environment, will allow slow delivery of the active agent onto the area being treated (col. 17, lines 20-23).

Applicants claim, "hardening the carrier into a tangible membrane" in claim 17. The instant claims differ from the prior art in that Youssefyeh do not specifically teach a "membrane" as instantly claimed. However, they nonetheless teach that the topical formulation is deposited onto the desired area and allowed to *form a film*, which will allow for slow release of active agent onto the treatment area. Thus, the "film" taught by Youssefyeh is functionally equivalent to the "membrane" claimed by Applicant.

Thus, the prior art teaches a method for treating immunological disorders as is instantly claimed. The method comprises topical administration of safflower oil in combination with a corticosteroid and a pharmaceutically acceptable carrier, whereby upon application, the formulation is deposited on the skin to form a film for the release of active agent onto the treatment area.

Youssefyeh each cellulose derivatives. (col. 15, lines 43-46). Youssefyeh do not teach that the film-forming carrier is nitrocellulose.

**Mantelle *et al.* ('363)** teach bioadhesive compositions in a flexible, finite form for topical application to skin or mucous membranes and methods for topical administration of active ingredients. See Abstract. The bioadhesive compositions comprise a mixture of at least two bioadhesive materials (col. 2, lines 30-41). Particularly suitable bioadhesive materials taught include cellulose materials such as nitrocellulose (col. 5, lines 40-55); (col. 6, lines 5-14). Mantelle teaches that such bioadhesive materials are effective for their swelling and absorption capabilities and provide enhanced and prolonged adherence to wet or moist surfaces, thereby increasing the effective penetration or absorption of the active ingredient (col. 4, lines 46-65).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the bioadhesive materials, such as nitrocellulose as taught by Mantelle within the delivery formulations of Youssefyeh et al. One of ordinary skill in the art would do so with a reasonable expectation of success because Mantelle teach that such bioadhesive materials (*i.e.*, nitrocellulose) are effective for their swelling and absorption capabilities and increase the effective penetration or absorption of an active ingredient. The expected result would an

enhanced method for treating dermatological disorders with maximum absorption of active agents.

* * * * *

**Claims 17-21, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Youssefyeh *et al.* (U.S. Pat. No. 5,968,519) in view of Brandt *et al.* (U.S. Pat. No. 6,627,216).**

The teachings of Youssefyeh are discussed above. Youssefyeh do not teach that the film-forming carrier is nitrocellulose.

**Brandt *et al.* ('216)** teach fluid compositions that are coated onto the surface of a host animal and then dried to form a covering element, such as a transdermal bandage, patch or the like (col. 1, lines 7-21). The fluid compositions include film-forming polymeric components of cellulosic polymers such as nitrocellulose. The polymer component (i.e., nitrocellulose) functions as a protective film covering (col. 10, line 46 – col. 11, line 9).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate cellulosic polymers, such as nitrocellulose as taught by Brandt within the delivery formulations of Youssefyeh et al. One of ordinary skill in the art would do so with a reasonable expectation of success because Brandt teach fluid compositions that dry to yield a coating whereby suitable materials that provide for the protective coating are nitrocellulose. The expected result would an improved method for treating dermatological disorders and conditions with enhanced delivery of active substances.

* * * * *

**Claims 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Youssefyeh *et al.* (U.S. Pat. No. 5,968,519) in view of Herb *et al.* (U.S. Pat. No. 5,534,246).**

The teachings of Youssefyeh are discussed above. Youssefyeh do not teach phenyltrimethicone and a vitamin.

**Herb *et al.* ('246)** teach topically-effective compositions comprising topically-active drugs that include dermatitis medications and psoriasis agents (see column 9, lines 46-51); (col. 10, lines 11-12). Herb *et al.* teach that nonvolatile organic compounds, such as phenyltrimethicone can also be added to the compositions to provide an aesthetic effect or for adjusting the refractive index (col. 12, lines 41-54); (Claims 20 & 35). Vitamins can also be included as a suitable topically-effective compound (see Table 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the dermatitic/psoriatic medications comprising the phenyltrimethicone organic compound and vitamins as taught by Herb *et al.* within the delivery formulations of Youssefyeh et al. One of ordinary skill in the art would do so with a reasonable expectation of success because Herb *et al.* explicitly teach that suitable and effective active agents for use in their formulation include vitamins as well as dermatitis and psoriasis medications to treat skin conditions and teach that organic compounds, such as phenyltrimethicone are added to the composition to provide aesthetically-based effects or alternatively, for the adjustment of refractive index values. The expected result would an enhanced method for treating dermatological disorders.

* * * * *

**Claims 17-21, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mantelle (U.S. Pat. No. 5,446,070) in view of Mantelle *et al.* (U.S. Pat. No. 6,562,363).**

**Mantelle ('070)** teaches flexible, finite, bioadhesive compositions for topical application comprising a therapeutically effective amount of a pharmaceutical agent(s), a pharmaceutically acceptable carrier and a solvent for the pharmaceutical agent(s) in the carrier and methods of administering the pharmaceutical agents (see Abstract); (col. 1, lines 18-34); (col. 4, line 24 – col. 5, line 62).

The composition when administered topically, for example to an area of the skin, delivers a pharmaceutical agent or a combination of agents to produce a local or systemic effect over a prolonged period of time (col. 5, line 65 – col. 6, line 3).

Suitable active agents disclosed for use in the invention include anti-inflammatory drugs, corticosteroids and the like (col. 23, line 32 – col. 41, line 39); claim 4; Examples 30-32.

Suitable adhesive carriers are disclosed at column 12, lines 55-65 and include cellulose derivatives, silicones.

Mantelle does not teach that the film-forming carrier is nitrocellulose.

**Mantelle *et al.* ('363)** teach bioadhesive compositions in a flexible, finite form for topical application to skin or mucous membranes and methods for topical administration of active ingredients. See Abstract. The bioadhesive compositions comprise a mixture of at least two bioadhesive materials (col. 2, lines 30-41). Particularly suitable bioadhesive materials taught

include cellulose materials such as nitrocellulose (col. 5, lines 40-55); (col. 6, lines 5-14). Mantelle teaches that such bioadhesive materials are effective for their swelling and absorption capabilities and provide enhanced and prolonged adherence to wet or moist surfaces, thereby increasing the effective penetration or absorption of the active ingredient (col. 4, lines 46-65).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the bioadhesive materials, such as nitrocellulose as taught by Mantelle ('363) within the formulations of Mantelle ('070). One of ordinary skill in the art would do so with a reasonable expectation of success because Mantelle teach that such bioadhesive materials (*i.e.*, nitrocellulose) are effective for their swelling and absorption capabilities and increase the effective penetration or absorption of an active ingredient. The expected result would an enhanced method for treating dermatological disorders with maximum absorption of active agents.

* * * * *

**Claims 17-21, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mantelle (U.S. Pat. No. 5,446,070) in view of Brandt *et al.* (U.S. Pat. No. 6,627,216).**

The teachings of Mantelle ('070) are discussed above. Mantelle do not teach that the film-forming carrier is nitrocellulose.

**Brandt *et al.* ('216)** teach fluid compositions that are coated onto the surface of a host animal and then dried to form a covering element, such as a transdermal bandage, patch or the like (col. 1, lines 7-21). The fluid compositions include film-forming polymeric components of cellulosic polymers such as nitrocellulose. The polymer component (i.e., nitrocellulose) functions as a protective film covering (col. 10, line 46 – col. 11, line 9).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate cellulosic polymers, such as nitrocellulose as taught by Brandt within the formulations of Mantelle. One of ordinary skill in the art would do so with a reasonable expectation of success because Brandt teach fluid compositions that dry to yield a coating whereby suitable materials that provide for the protective coating are nitrocellulose. The expected result would an improved method for treating dermatological disorders and conditions with enhanced delivery of active substances.

* * * * *

**Claims 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mantelle (U.S. Pat. No. 5,446,070) in view of Herb *et al.* (U.S. Pat. No. 5,534,246).**

The teachings of Mantelle ('070) are discussed above. Mantelle does not teach phenyltrimethicone.

**Herb *et al.* ('246)** teach topically-effective compositions comprising topically-active drugs that include dermatitis medications and psoriasis agents (see column 9, lines 46-51); (col. 10, lines 11-12). Herb *et al.* teach that nonvolatile organic compounds, such as phenyltrimethicone can also be added to the compositions to provide an aesthetic effect or for adjusting the refractive index (col. 12, lines 41-54); (Claims 20 & 35).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the dermatitic/psoriatic medications comprising the phenyltrimethicone organic compound as taught by Herb *et al.* within the formulations of Mantelle. One of ordinary skill in the art would do so with a reasonable expectation of success because Herb *et al.*

explicitly teach that suitable and effective active agents for use in their formulation include dermatitis and psoriasis medications to treat skin conditions and teach that organic compounds, such as phenyltrimethicone are added to the composition to provide aesthetically-based effects or alternatively, for the adjustment of refractive index values. The expected result would an enhanced composition and method for treating skin disorders.

***Response to Arguments***

Applicant's arguments, see Response, filed 04/28/08, with respect to the rejection(s) of claim(s) 17-29 over Youssefyeh (USPN 5,968,519) and Mantelle (USPN 5,446,070) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the Mantelle et al. ('363) and Brandt et al. ('216) references in combination with the Youssefyeh ('519) and Mantelle ('070) references.

Regarding the Declaration under 37 C.F.R.1.132 filed 04/28/08, the Declaration has been fully considered. Applicant states that the "use of nitrocellulose as the film-forming carrier shows a superior level of blanching of hydrocortisone into the skin when compared with other film-forming cellulose carriers." This was found persuasive with respect to the Youssefyeh ('519) and Mantelle ('070) references, as Youssefyeh and Mantelle do not teach the inclusion of nitrocellulose. However, the rejection has now been reformulated to include the Mantelle et al. ('363) and Brandt ('216) references. These references establish and teach the use of cellulosic polymers, such as nitrocellulose and teach that it is a particularly suitable material, known for its' effective absorption, swelling and penetration properties.

### *Conclusion*

--No claims are allowed at this time.

### Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley, can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1618

*hns*

August 04, 2008